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PFIZER INC.

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX MARKETING, )	MDL Docket No. 1699
SALES PRACTICES AND PRODUCTS )	
LIABILITY LITIGATION )	CASE NO 3:08-cv-02910-CRB
<i>This document relates to</i> )	
MARIE MAKI, )	<b>PFIZER INC.'S ANSWER TO</b>
Plaintiff, )	<b>COMPLAINT</b>
vs. )	<b>JURY DEMAND ENDORSED</b>
PFIZER, INC., )	<b>HEREIN</b>
Defendant. )	

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

## I.

**PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra ®.

## II.

**ORIGINAL ANSWER****Response to Allegations Regarding Jurisdiction**

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

**Response to Allegations Regarding the Nature of the Case**

2. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

4. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

5. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

6. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

7. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

**Response to Allegations Regarding Parties**

8. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

9. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

10. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies that Bextra® caused Plaintiff injury or damages and denies the remaining allegations in this paragraph of the Complaint.

11. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

12. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

13. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

14. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

15. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

1 16. Defendant admits that it does business in the United States, including New York.  
2 Defendant denies the remaining allegations in this paragraph of the Complaint.

3 17. Defendant admits that, during certain periods of time, it marketed and co-promoted  
4 Bextra® in the United States to be prescribed by healthcare providers who are by law  
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies  
6 the remaining allegations in this paragraph of the Complaint.

7 18. Defendant admits that it is registered to do and does business in New York. Defendant  
8 is without knowledge or information sufficient to form a belief as to the judicial district in  
9 which the asserted claims allegedly arose, and, therefore, denies the same. Defendant denies  
10 any wrongful conduct, denies committing a tort in the States of New York or California, and  
11 denies the remaining allegations in this paragraph of the Complaint.

12 **Response to Factual Allegations**

13 19. Defendant admits that Bextra® was approved by the FDA, on November 16, 2001.  
14 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is  
15 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
16 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining  
17 allegations in this paragraph of the Complaint.

18 20. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-  
19 steroidal anti-inflammatory drugs (“NSAIDs”). Defendant states that the remaining allegations  
20 in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no  
21 response is required. To the extent that a response is deemed required, Defendant states that  
22 Plaintiff fails to provide the context for the remaining allegations in this paragraph of the  
23 Complaint. Defendant is therefore without knowledge or information sufficient to form a belief  
24 as to the truth of such allegations, and, therefore, denies the same.

25 21. Defendant states that, as stated in the FDA-approved labeling for Bextra®, “[t]he  
26 mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily  
27 through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in  
28 humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1).” Defendant states that the

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1 remaining allegations in this paragraph of the Complaint are not directed toward Defendant,  
2 and, therefore, no response is required. To the extent that a response is deemed required,  
3 Defendant states that Plaintiff fails to provide the context for the remaining allegations in this  
4 paragraph of the Complaint. Defendant is therefore without knowledge or information  
5 sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same.

6 22. Defendant states that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendant states that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
11 of the Complaint.

12 23. Defendant states that the referenced media statement speaks for itself and respectfully  
13 refers the Court to the media statement for its actual language and full text. Any attempt to  
14 characterize the media statement is denied. Defendant denies the remaining allegations in this  
15 paragraph of the Complaint.

16 24. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S.  
17 market as of April 7, 2005. Defendant denies any wrongful conduct and denies the remaining  
18 allegations in this paragraph of the Complaint.

19 25. Defendant admits that, during certain periods of time, it marketed and co-promoted  
20 Bextra® in the United States to be prescribed by healthcare providers who are by law  
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant  
22 admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for  
23 use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as  
24 well as for the treatment of primary dysmenorrhea. Defendant denies the remaining  
25 allegations in this paragraph of the Complaint.

26 26. Defendant is without knowledge or information sufficient to form a belief as to the truth  
27 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
28 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

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1 when used in accordance with its FDA-approved prescribing information. Defendant states that  
2 the potential effects of Bextra® were and are adequately described in its FDA-approved  
3 prescribing information, which was at all times adequate and comported with applicable  
4 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
5 allegations in this paragraph of the Complaint.

6 27. Defendant is without knowledge or information sufficient to form a belief as to the truth  
7 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
8 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
9 when used in accordance with its FDA-approved prescribing information. Defendant states that  
10 the potential effects of Bextra® were and are adequately described in its FDA-approved  
11 prescribing information, which was at all times adequate and comported with applicable  
12 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
13 allegations in this paragraph of the Complaint.

14 28. Defendant is without knowledge or information sufficient to form a belief as to the truth  
15 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
16 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
17 when used in accordance with its FDA-approved prescribing information. Defendant states that  
18 the potential effects of Bextra® were and are adequately described in its FDA-approved  
19 prescribing information, which was at all times adequate and comported with applicable  
20 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is  
21 unreasonably dangerous, and denies the remaining allegations in this paragraph of the  
22 Complaint.

23 29. Defendant is without knowledge or information sufficient to form a belief as to the truth  
24 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
25 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
26 when used in accordance with its FDA-approved prescribing information. Defendant states that  
27 the potential effects of Bextra® were and are adequately described in its FDA-approved  
28 prescribing information, which was at all times adequate and comported with applicable



standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

**Response to First Cause of Action: Negligence and Negligence Per Se**

30. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

31. Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

32. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

33. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

34. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of



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1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
4 of the Complaint.

5 35. Defendant states that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendant states that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and  
10 denies the remaining allegations in this paragraph of the Complaint.

11 36. Defendant is without knowledge or information sufficient to form a belief as to the truth  
12 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
13 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
14 when used in accordance with its FDA-approved prescribing information. Defendant states that  
15 the potential effects of Bextra® were and are adequately described in its FDA-approved  
16 prescribing information, which was at all times adequate and comported with applicable  
17 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused  
18 Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the  
19 Complaint.

20 37. Defendant is without knowledge or information sufficient to form a belief as to the truth  
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
22 and, therefore, denies the same. Defendant admits that, during certain periods of time, it  
23 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare  
24 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
25 FDA. Defendant states that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendant states that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of  
2 April 7, 2005. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably  
3 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

4 38. Defendant is without knowledge or information sufficient to form a belief as to the truth  
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
6 and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®  
7 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the  
8 Complaint.

9 39. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
10 damages, and denies the remaining allegations in this paragraph of the Complaint.

11 40. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
12 damages, and denies the remaining allegations in this paragraph of the Complaint.

13 41. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
14 damages, and denies the remaining allegations in this paragraph of the Complaint.

15 42. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
16 damages, and denies the remaining allegations in this paragraph of the Complaint.

17 **Response to Second Cause of Action: Strict Products Liability**

18 43. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
19 Complaint as if fully set forth herein.

20 44. Defendant is without knowledge or information sufficient to form a belief as to the truth  
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
22 and, therefore, denies the same. Defendant admits that, during certain periods of time, it  
23 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare  
24 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
25 FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

26 45. Defendant admits that, during certain periods of time, it marketed and co-promoted  
27 Bextra® in the United States to be prescribed by healthcare providers who are by law  
28 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states

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1 that, in the ordinary case, Bextra® was expected to reach users and consumers without  
2 substantial change from the time of sale. Defendant denies the remaining allegations in this  
3 paragraph of the Complaint.

4 46. Defendant is without knowledge or information sufficient to form a belief as to the truth  
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
7 when used in accordance with its FDA-approved prescribing information. Defendant states that  
8 the potential effects of Bextra® were and are adequately described in its FDA-approved  
9 prescribing information, which was at all times adequate and comported with applicable  
10 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is  
11 defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of  
12 the Complaint.

13 47. Defendant states that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendant states that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
18 remaining allegations in this paragraph of the Complaint.

19 48. Defendant is without knowledge or information sufficient to form a belief as to the truth  
20 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
21 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
22 when used in accordance with its FDA-approved prescribing information. Defendant denies  
23 any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies  
24 the remaining allegations in this paragraph of the Complaint.

25 49. Defendant states that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,  
27 denies that Bextra® is defective or unreasonably dangerous, and denies the remaining  
28 allegations in this paragraph of the Complaint.

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1 50. Defendant states that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,  
3 denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the  
4 Complaint.

5 51. Defendant is without knowledge or information sufficient to form a belief as to the truth  
6 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
7 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
8 when used in accordance with its FDA-approved prescribing information. Defendant states that  
9 the potential effects of Bextra® were and are adequately described in its FDA-approved  
10 prescribing information, which was at all times adequate and comported with applicable  
11 standards of care and law. Defendant denies the remaining allegations in this paragraph of the  
12 Complaint.

13 52. Defendant is without knowledge or information sufficient to form a belief as to the truth  
14 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
15 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
16 when used in accordance with its FDA-approved prescribing information. Defendant states that  
17 the potential effects of Bextra® were and are adequately described in its FDA-approved  
18 prescribing information, which was at all times adequate and comported with applicable  
19 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
20 allegations in this paragraph of the Complaint.

21 53. Defendant states that this paragraph of the Complaint contains legal contentions to  
22 which no response is required. To the extent that a response is deemed required, Defendant  
23 admits that it had duties as are imposed by law but denies having breached such duties.  
24 Defendant states that Bextra® was and is safe and effective when used in accordance with its  
25 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®  
26 were and are adequately described in its FDA-approved prescribing information, which was at  
27 all times adequate and comported with applicable standards of care and law. Defendant denies  
28 any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the

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1 remaining allegations in this paragraph of the Complaint.

2 54. Defendant states that Bextra® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendant states that the potential effects of  
4 Bextra® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and  
7 denies the remaining allegations in this paragraph of the Complaint.

8 55. Defendant is without knowledge or information sufficient to form a belief as to the truth  
9 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
10 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
11 when used in accordance with its FDA-approved prescribing information. Defendant states that  
12 the potential effects of Bextra® were and are adequately described in its FDA-approved  
13 prescribing information, which was at all times adequate and comported with applicable  
14 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is  
15 defective or unreasonably dangerous, denies that Bextra® caused Plaintiff injury or damages,  
16 and denies the remaining allegations in this paragraph of the Complaint.

17 56. Defendant states that Bextra® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendant states that the potential effects of  
19 Bextra® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
22 remaining allegations in this paragraph of the Complaint.

23 57. Defendant states that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendant states that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
28 remaining allegations in this paragraph of the Complaint.

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1 58. Defendant states that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendant states that the potential effects of  
3 Bextra® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
6 remaining allegations in this paragraph of the Complaint.

7 59. Defendant is without knowledge or information sufficient to form a belief as to the truth  
8 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
9 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
10 when used in accordance with its FDA-approved prescribing information. Defendant states that  
11 the potential effects of Bextra® were and are adequately described in its FDA-approved  
12 prescribing information, which was at all times adequate and comported with applicable  
13 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is  
14 defective, and denies the remaining allegations in this paragraph of the Complaint.

15 60. Defendant states that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendant states that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®  
20 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the  
21 Complaint.

22 61. Defendant states that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendant states that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
27 remaining allegations in this paragraph of the Complaint.

28 62. Defendant states that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of  
2 Bextra® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®  
5 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the  
6 Complaint.

7 63. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
8 damages, and denies the remaining allegations in this paragraph of the Complaint.

9 64. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
10 damages, and denies the remaining allegations in this paragraph of the Complaint.

11 65. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
12 damages, and denies the remaining allegations in this paragraph of the Complaint.

13 **Response to Third Cause of Action: Breach of Express Warranty**

14 66. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
15 Complaint as if fully set forth herein.

16 67. Defendant states that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendant states that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.  
21 Defendant denies the remaining allegations in this paragraph of the Complaint.

22 68. Defendant states that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendant states that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
27 of the Complaint.

28 69. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or



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1 damages, and denies the remaining allegations in this paragraph of the Complaint.

2 70. Defendant admits that it provided FDA-approved prescribing information regarding  
3 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

4 71. Defendant admits that it provided FDA-approved prescribing information regarding  
5 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

6 72. Defendant states that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendant states that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
11 remaining allegations in this paragraph of the Complaint.

12 73. Defendant states that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendant states that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.  
17 Defendant denies the remaining allegations in this paragraph of the Complaint.

18 74. Defendant states that Bextra® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendant states that the potential effects of  
20 Bextra® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
23 of the Complaint.

24 75. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
25 damages, and denies the remaining allegations in this paragraph of the Complaint.

26 76. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
27 damages, and denies the remaining allegations in this paragraph of the Complaint.

28 77. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or

1 damages, and denies the remaining allegations in this paragraph of the Complaint.

2 78. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
3 damages, and denies the remaining allegations in this paragraph of the Complaint.

4 **Response to Fourth Cause of Action: Breach of Implied Warranties**

5 79. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
6 Complaint as if fully set forth herein.

7 80. Defendant admits that, during certain periods of time, it marketed and co-promoted  
8 Bextra® in the United States to be prescribed by healthcare providers who are by law  
9 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies  
10 the remaining allegations in this paragraph of the Complaint.

11 81. Defendant is without knowledge or information sufficient to form a belief as to the truth  
12 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
13 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
14 when used in accordance with its FDA-approved prescribing information. Defendant states that  
15 the potential effects of Bextra® were and are adequately described in its FDA-approved  
16 prescribing information, which was at all times adequate and comported with applicable  
17 standards of care and law. Defendant admits that it provided FDA-approved prescribing  
18 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph  
19 of the Complaint.

20 82. Defendant states that Bextra® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendant states that the potential effects of  
22 Bextra® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.  
25 Defendant denies the remaining allegations in this paragraph of the Complaint.

26 83. Defendant states that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendant states that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably  
3 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

4 84. Defendant is without knowledge or information sufficient to form a belief as to the truth  
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
7 when used in accordance with its FDA-approved prescribing information. Defendant states that  
8 the potential effects of Bextra® were and are adequately described in its FDA-approved  
9 prescribing information, which was at all times adequate and comported with applicable  
10 standards of care and law. Defendant admits that it provided FDA-approved prescribing  
11 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph  
12 of the Complaint.

13 85. Defendant is without knowledge or information sufficient to form a belief as to the truth  
14 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
15 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
16 when used in accordance with its FDA-approved prescribing information. Defendant states that  
17 the potential effects of Bextra® were and are adequately described in its FDA-approved  
18 prescribing information, which was at all times adequate and comported with applicable  
19 standards of care and law. Defendant admits that it provided FDA-approved prescribing  
20 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph  
21 of the Complaint.

22 86. Defendant states that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendant states that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers  
27 without substantial change from the time of sale. Defendant denies any wrongful conduct,  
28 denies that Bextra® is defective or unreasonably dangerous, and denies remaining allegations in

1 this paragraph of the Complaint.

2 87. Defendant states that Bextra® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendant states that the potential effects of  
4 Bextra® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendant denies any wrongful conduct and denies remaining allegations in this paragraph of  
7 the Complaint.

8 88. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
9 damages, and denies the remaining allegations in this paragraph of the Complaint.

10 89. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
11 damages, and denies the remaining allegations in this paragraph of the Complaint.

12 90. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
13 damages, and denies the remaining allegations in this paragraph of the Complaint.

14 91. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
15 damages, and denies the remaining allegations in this paragraph of the Complaint.

16 **Response to Fifth Cause of Action: Fraudulent Misrepresentation**

17 92. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
18 Complaint as if fully set forth herein.

19 93. Defendant states that Bextra® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendant states that the potential effects of  
21 Bextra® were and are adequately described in its FDA-approved prescribing information,  
22 which was at all times adequate and comported with applicable standards of care and law.  
23 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
24 of the Complaint.

25 94. Defendant states that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendant states that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
2 of the Complaint.

3 95. Defendant states that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendant states that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
8 of the Complaint.

9 96. Defendant is without knowledge or information sufficient to form a belief as to the truth  
10 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
11 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
12 when used in accordance with its FDA-approved prescribing information. Defendant states that  
13 the potential effects of Bextra® were and are adequately described in its FDA-approved  
14 prescribing information, which was at all times adequate and comported with applicable  
15 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
16 allegations in this paragraph of the Complaint.

17 97. Defendant is without knowledge or information sufficient to form a belief as to the truth  
18 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
19 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
20 when used in accordance with its FDA-approved prescribing information. Defendant states that  
21 the potential effects of Bextra® were and are adequately described in its FDA-approved  
22 prescribing information, which was at all times adequate and comported with applicable  
23 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused  
24 Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the  
25 Complaint.

26 98. Defendant states that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendant states that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the  
3 remaining allegations in this paragraph of the Complaint.

4 99. Defendant states that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendant states that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
9 of the Complaint.

10 100. Defendant admits that, during certain periods of time, it marketed and co-promoted  
11 Bextra® in the United States to be prescribed by healthcare providers who are by law  
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies  
13 any wrongful conduct, denies that Bextra® caused Plaintiff injury or damages, and denies the  
14 remaining allegations in this paragraph of the Complaint.

15 101. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
16 damages, and denies the remaining allegations in this paragraph of the Complaint.

17 102. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
18 damages, and denies the remaining allegations in this paragraph of the Complaint.

19 103. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
20 damages, and denies the remaining allegations in this paragraph of the Complaint.

21 **Response to Sixth Cause of Action: Fraudulent Concealment**

22 104. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
23 Complaint as if fully set forth herein.

24 105. Defendant states that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendant states that the potential effects of  
26 Bextra® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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of the Complaint.

106. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

107. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

108. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

109. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is



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1 defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining  
2 allegations in this paragraph of the Complaint.

3 110. Defendant is without knowledge or information sufficient to form a belief as to the truth  
4 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
5 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
6 when used in accordance with its FDA-approved prescribing information. Defendant states that  
7 the potential effects of Bextra® were and are adequately described in its FDA-approved  
8 prescribing information, which was at all times adequate and comported with applicable  
9 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
10 allegations in this paragraph of the Complaint.

11 111. Defendant states that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendant states that the potential effects of  
13 Bextra® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.  
15 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
16 of the Complaint.

17 112. Defendant is without knowledge or information sufficient to form a belief as to the truth  
18 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
19 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
20 when used in accordance with its FDA-approved prescribing information. Defendant states that  
21 the potential effects of Bextra® were and are adequately described in its FDA-approved  
22 prescribing information, which was at all times adequate and comported with applicable  
23 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
24 allegations in this paragraph of the Complaint.

25 113. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
26 damages, and denies the remaining allegations in this paragraph of the Complaint.

27 114. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
28 damages, and denies the remaining allegations in this paragraph of the Complaint.

1 115. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
2 damages, and denies the remaining allegations in this paragraph of the Complaint.

3 **Response to Seventh Cause of Action: Negligent Misrepresentation**

4 116. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
5 Complaint as if fully set forth herein.

6 117. Defendant states that this paragraph of the Complaint contains legal contentions to  
7 which no response is required. To the extent that a response is deemed required, Defendant  
8 admits that it had duties as are imposed by law but denies having breached such duties.  
9 Defendant states that Bextra® was and is safe and effective when used in accordance with its  
10 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®  
11 were and are adequately described in its FDA-approved prescribing information, which was at  
12 all times adequate and comported with applicable standards of care and law. Defendant denies  
13 the remaining allegations in this paragraph of the Complaint.

14 118. Defendant states that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendant states that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
19 of the Complaint.

20 119. Defendant states that Bextra® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendant states that the potential effects of  
22 Bextra® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and  
25 denies the remaining allegations in this paragraph of the Complaint.

26 120. Defendant states that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendant states that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
3 of the Complaint.

4 121. Defendant states that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendant states that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and  
9 denies the remaining allegations in this paragraph of the Complaint.

10 122. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
11 damages, and denies the remaining allegations in this paragraph of the Complaint.

12 123. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
13 damages, and denies the remaining allegations in this paragraph of the Complaint.

14 124. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
15 damages, and denies the remaining allegations in this paragraph of the Complaint.

16 **Response to Eighth Cause of Action: Fraud and Deceit**

17 125. Defendant incorporates by reference its responses to each paragraph of Plaintiff's  
18 Complaint as if fully set forth herein.

19 126. Defendant states that Plaintiff fails to provide the proper context for the allegations in  
20 this paragraph of the Complaint. Defendant therefore lacks knowledge or information  
21 sufficient to form a belief as to the truth of such allegations and, therefore, denies the same.

22 127. Defendant states that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendant states that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
27 of the Complaint.

28 128. Defendant denies any wrongful conduct and denies the remaining allegations in this

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1 paragraph of the Complaint.

2 129. Defendant states that this paragraph of the Complaint contains legal contentions to  
3 which no response is required. To the extent that a response is deemed required, Defendant  
4 admits that it had duties as are imposed by law but denies having breached such duties.  
5 Defendant denies the remaining allegations in this paragraph of the Complaint.

6 130. Defendant states that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendant states that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
11 of the Complaint.

12 131. Defendant states that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendant states that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendant denies the remaining allegations in this paragraph of the Complaint.

17 132. Defendant states that Bextra® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendant states that the potential effects of  
19 Bextra® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
22 of the Complaint.

23 133. Defendant states that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendant states that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
28 of the Complaint.

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1 134. Defendant states that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendant states that the potential effects of  
3 Bextra® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
6 of the Complaint.

7 135. Defendant states that Bextra® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendant states that the potential effects of  
9 Bextra® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
12 of the Complaint.

13 136. Defendant states that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendant states that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
18 of the Complaint.

19 137. Defendant states that Bextra® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendant states that the potential effects of  
21 Bextra® were and are adequately described in its FDA-approved prescribing information,  
22 which was at all times adequate and comported with applicable standards of care and law.  
23 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
24 of the Complaint.

25 138. Defendant states that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendant states that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
2 of the Complaint.

3 139. Defendant states that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendant states that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.

7 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
8 of the Complaint.

9 140. Defendant states that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendant states that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.

13 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
14 of the Complaint.

15 141. Defendant states that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendant states that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.

19 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
20 of the Complaint.

21 142. Defendant states that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendant states that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.

25 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
26 of the Complaint.

27 143. Defendant states that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
4 of the Complaint.

5 144. Defendant states that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendant states that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
10 of the Complaint.

11 145. Defendant states that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendant states that the potential effects of  
13 Bextra® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.  
15 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
16 of the Complaint.

17 146. Defendant denies any wrongful conduct and denies the remaining allegations in this  
18 paragraph of the Complaint.

19 147. Defendant admits that, during certain periods of time, it marketed and co-promoted  
20 Bextra® in the United States to be prescribed by healthcare providers who are by law  
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies  
22 the remaining allegations in this paragraph of the Complaint.

23 148. Defendant states that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendant states that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
28 of the Complaint.



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1 149. Defendant states that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendant states that the potential effects of  
3 Bextra® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph  
6 of the Complaint.

7 150. Defendant is without knowledge or information sufficient to form a belief as to the truth  
8 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,  
9 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective  
10 when used in accordance with its FDA-approved prescribing information. Defendant states that  
11 the potential effects of Bextra® were and are adequately described in its FDA-approved  
12 prescribing information, which was at all times adequate and comported with applicable  
13 standards of care and law. Defendant denies any wrongful conduct and denies the remaining  
14 allegations in this paragraph of the Complaint.

15 151. Defendant denies any wrongful conduct and denies the remaining allegations in this  
16 paragraph of the Complaint.

17 152. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
18 damages, and denies the remaining allegations in this paragraph of the Complaint.

19 153. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
20 damages, and denies the remaining allegations in this paragraph of the Complaint.

21 154. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
22 damages, and denies the remaining allegations in this paragraph of the Complaint.

23 **Response to Prayer for Relief**

24 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or  
25 damages, and denies the remaining allegations in Plaintiff's Prayer for Relief, including all  
26 subparts.

1 **III.**

2 **GENERAL DENIAL**

3 Defendant denies the allegations and/or legal conclusions set forth in Plaintiff's Complaint that  
4 have not been previously admitted, denied, or explained.

5 **IV.**

6 **AFFIRMATIVE DEFENSES**

7 Defendant reserves the right to rely upon any of the following or additional defenses to  
8 claims asserted by Plaintiff to the extent that such defenses are supported by information  
9 developed through discovery or evidence at trial. Defendant affirmatively shows that:

10 **First Defense**

11 1. The Complaint fails to state a claim upon which relief can be granted.

12 **Second Defense**

13 2. Bextra® is prescription medical product. The federal government has preempted the  
14 field of law applicable to the labeling and warning of prescription medical products.  
15 Defendant's labeling and warning of Bextra® was at all times in compliance with applicable  
16 federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon  
17 which relief can be granted; such claims, if allowed, would conflict with applicable federal  
18 law and violate the Supremacy Clause of the United States Constitution.

19 **Third Defense**

20 3. At all relevant times, Defendant provided proper warnings, information and  
21 instructions for the drug in accordance with generally recognized and prevailing standards in  
22 existence at the time.

23 **Fourth Defense**

24 4. At all relevant times, Defendant's warnings and instructions with respect to the use of  
25 Bextra® conformed to the generally recognized, reasonably available, and reliable state of  
26 knowledge at the time the drug was manufactured, marketed and distributed.

27 **Fifth Defense**

28 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

2 **Sixth Defense**

3 6. Plaintiff's action is barred by the statute of repose.

4 **Seventh Defense**

5 7. Plaintiff's claims against Defendant are barred to the extent Plaintiff was contributorily  
6 negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any  
7 recovery by Plaintiff should be diminished accordingly.

8 **Eighth Defense**

9 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or  
10 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the  
11 part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not  
12 liable in any way.

13 **Ninth Defense**

14 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,  
15 intervening causes for which Defendant cannot be liable.

16 **Tenth Defense**

17 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were  
18 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or  
19 act of God.

20 **Eleventh Defense**

21 11. Defendant affirmatively denies that it violated any duty owed to Plaintiff.

22 **Twelfth Defense**

23 12. A manufacturer has no duty to warn patients or the general public of any risk,  
24 contraindication, or adverse effect associated with the use of a prescription medical product.  
25 Rather, the law requires that all such warnings and appropriate information be given to the  
26 prescribing physician and the medical profession, which act as a "learned intermediary" in  
27 determining the use of the product. Bextra® is a prescription medical product, available only  
28 on the order of a licensed physician. Bextra® provided adequate warnings to Plaintiff's

1 treating and prescribing physicians.

2 **Thirteenth Defense**

3 13. The product at issue was not in a defective condition or unreasonably dangerous at the  
4 time it left the control of the manufacturer or seller.

5 **Fourteenth Defense**

6 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit  
7 for its intended use and the warnings and instructions accompanying Bextra® at the time of  
8 the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved  
9 usages.

10 **Fifteenth Defense**

11 15. Plaintiff's causes of action are barred, in whole or in part, by the lack of a defect as the  
12 Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable  
13 standard of care.

14 **Sixteenth Defense**

15 16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use  
16 of the product Bextra® after the product left the control of Defendant and any liability of  
17 Defendant is therefore barred.

18 **Seventeenth Defense**

19 17. Plaintiff's alleged injuries/damages were not caused by any failure to warn on the part  
20 of Defendant.

21 **Eighteenth Defense**

22 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent  
23 conditions unrelated to Bextra®.

24 **Nineteenth Defense**

25 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore,  
26 the doctrine of assumption of the risk bars or diminishes any recovery.

27 **Twentieth Defense**

28 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are

preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiff's claims are barred, in whole or in part, under the applicable state law because the subject pharmaceutical product at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

**Twenty-third Defense**

23. Plaintiff's claims are barred, in whole or in part, by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiff's claims are barred, in whole or in part, because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiff's claims are barred, in whole or in part, because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiff's claims are barred, in whole or in part, because the subject pharmaceutical

1 product at issue “provides net benefits for a class of patients” within the meaning of  
2 Restatement (Third) of Torts: Products Liability, § 6, Comment f.

3 **Twenty-eighth Defense**

4 28. Plaintiff’s claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
5 Products Liability.

6 **Twenty-ninth Defense**

7 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead  
8 facts sufficient under the law to justify an award of punitive damages.

9 **Thirtieth Defense**

10 30. Defendant affirmatively avers that the imposition of punitive damages in this case  
11 would violate Defendant’s rights to procedural due process under the Fourteenth Amendment  
12 of the United States Constitution and the Constitutions of the States of California and  
13 Michigan, and would additionally violate Defendant’s rights to substantive due process under  
14 the Fourteenth Amendment of the United States Constitution.

15 **Thirty-first Defense**

16 31. Plaintiff’s claims for punitive damages are barred, in whole or in part, by the Fifth and  
17 Fourteenth Amendments to the United States Constitution.

18 **Thirty-second Defense**

19 32. The imposition of punitive damages in this case would violate the First Amendment to  
20 the United States Constitution.

21 **Thirty-third Defense**

22 33. Plaintiff’s punitive damage claims are preempted by federal law.

23 **Thirty-fourth Defense**

24 34. In the event that reliance was placed upon Defendant’s nonconformance to an express  
25 representation, this action is barred as there was no reliance upon representations, if any, of  
26 Defendant.

27 **Thirty-fifth Defense**

28 35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance

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1 to any express representation.

2 **Thirty-sixth Defense**

3 36. To the extent that Plaintiff's claims are based on a theory providing for liability  
4 without proof of causation, the claims violate Defendant's rights under the United States  
5 Constitution.

6 **Thirty-seventh Defense**

7 37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any,  
8 and labeling with respect to the subject pharmaceutical product were not false or misleading  
9 and, therefore, constitute protected commercial speech under the applicable provisions of the  
10 United States Constitution.

11 **Thirty-eighth Defense**

12 38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly  
13 caused injuries asserted in the Complaint, punitive damages are barred or reduced by  
14 applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the  
15 due process protections afforded by the United States Constitution, the excessive fines clause  
16 of the Eighth Amendment of the United States Constitution, the Commerce Clause of the  
17 United States Constitution, and the Full Faith and Credit Clause of the United States  
18 Constitution, and applicable provisions of the Constitutions of the States of Michigan and  
19 California. Any law, statute, or other authority purporting to permit the recovery of punitive  
20 damages in this case is unconstitutional, facially and as applied, to the extent that, without  
21 limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's  
22 discretion in determining whether to award punitive damages and/or the amount, if any; (2) is  
23 void for vagueness in that it failed to provide adequate advance notice as to what conduct will  
24 result in punitive damages; (3) permits recovery of punitive damages based on out-of-state  
25 conduct, conduct that complied with applicable law, or conduct that was not directed, or did  
26 not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an  
27 amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff  
28 and to the amount of compensatory damages, if any; (5) permits jury consideration of net



worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

### **Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package inserts and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

### **Fortieth Defense**

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

### **Forty-first Defense**

41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

### **Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

### **Forty-third Defense**

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,

1 waiver, and/or estoppel.

2 **Forty-fourth Defense**

3 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the  
4 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or  
5 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were  
6 independent of or far removed from Defendant's conduct.

7 **Forty-fifth Defense**

8 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®  
9 did not proximately cause injuries or damages to Plaintiff.

10 **Forty-sixth Defense**

11 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff  
12 did not incur any ascertainable loss as a result of Defendant's conduct.

13 **Forty-seventh Defense**

14 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
15 manufacturing, labeling, packaging, and any advertising of the product complied with the  
16 applicable codes, standards and regulations established, adopted, promulgated or approved by  
17 any applicable regulatory body, including but not limited to the United States, any state, and  
18 any agency thereof.

19 **Forty-eighth Defense**

20 48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the  
21 product labeling contained the information that Plaintiff contends should have been provided.

22 **Forty-ninth Defense**

23 49. The claims asserted in the Complaint are barred because the utility of Bextra®  
24 outweighed its risks.

25 **Fiftieth Defense**

26 50. Plaintiff's damages, if any, are barred or limited by the payments received from  
27 collateral sources.

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1 **Fifty-first Defense**

2 51. Defendant's liability, if any, can only be determined after the percentages of  
3 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if  
4 any, are determined. Defendant seeks an adjudication of the percentage of fault of the  
5 claimants and each and every other person whose fault could have contributed to the alleged  
6 injuries and damages, if any, of Plaintiff.

7 **Fifty-second Defense**

8 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that  
9 the common law gives deference to discretionary actions by the United States Food and Drug  
10 Administration under the Federal Food, Drug, and Cosmetic Act.

11 **Fifty-third Defense**

12 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®  
13 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act  
14 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's  
15 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the  
16 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,  
17 and with the specific determinations by FDA specifying the language that should be used in  
18 the labeling accompanying Bextra. Accordingly, Plaintiff's claims are preempted by the  
19 Supremacy Clause of the United States Constitution, Art. VI, cl. 2, and the laws of the United  
20 States.

21 **Fifty-fourth Defense**

22 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity  
23 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

24 **Fifty-fifth Defense**

25 55. Defendant states on information and belief that the Complaint and each purported  
26 cause of action contained therein is barred by the statutes of limitations contained in California  
27 Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of  
28 limitation as may apply.

**Fifty-sixth Defense**

56. Defendant states on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

**Fifty-seventh Defense**

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

**Fifty-eighth Defense**

58. The product in question was approved as safe and effective by the FDA and the labeling for said product was in compliance with FDA's approval at the time the products left the control of Defendant and hence, Plaintiff's claims are barred by MCL 600.2946(5).

**Fifty-ninth Defense**

59. Plaintiff's claim for non-economic damages is capped pursuant to MCL 600.2946a.

**Sixtieth Defense**

60. To the extent Plaintiff proves that the product in question caused or contributed to any injury Plaintiff may have suffered, which is denied by Defendant, Defendant should not be liable to warn as Plaintiff cannot prove that the scientific, technical, or medical information that was reasonably available at the time was known or should have been known by the Defendant. MCL 600.2948.

**Sixty-first Defense**

61. Defendant asserts all of the protections and defenses afforded Defendant, and Plaintiff's claims of liability or damages are limited pursuant to the Michigan Products Liability Act including specifically, but not limited to MCL 600.2946 through MCL 600.6306, including MCL 600.2946, MCL 600.2946(a), MCL 600.2947, MCL 600.2948, MCL 600.2956, MCL 600.2957 and MCL 600.2959.

**Sixty-second Defense**

62. The product alleged to have caused damages may not have been used in the manner and for the purposes intended. Such improper use and/or abuse of the product for an unforeseeable purpose and in an unforeseeable manner may have proximately caused or contributed to the alleged injuries, if any, and therefore there is no recovery available against Defendant pursuant to MCL 600.2947.

**Sixty-third Defense**

63. Plaintiff's claim for non-economic damages is barred for the reason that Plaintiff's percentage of comparative fault is greater than the aggregate fault of the Defendant and non-parties hereto, pursuant to MCL 600.2959 and MCL 600.6306; but that to the extent allowable, must be reduced in total or part pursuant to 600.2946(a).

**Sixty-fourth Defense**

64. The claims set forth in Plaintiff's Complaint are barred in that the product in question was provided to a sophisticated user. In this case, the "user" would include any prescribing physician.

**Sixty-fifth Defense**

65. Plaintiff failed to make every reasonable effort to mitigate, prevent and/or reduce Plaintiff's alleged damages, injuries, and monetary losses.

**Sixty-sixth Defense**

66. Plaintiff's claims, part of Plaintiff's claims, or evidence relating to Plaintiff's claims may be barred, in whole or in part, due to possible spoliation of evidence by Plaintiff, or those within Plaintiff's control, or with full knowledge of Plaintiff.

**Sixty-seventh Defense**

67. Any claims for punitive damages are barred in that they are not allowable under Michigan law. To the extent that they are allowed contrary to Michigan law, such claims further violate Defendant's constitutional rights under the following clauses of the United States Constitution, as well as any similar provisions under the Michigan Constitution: Commerce Clause, Contracts Clause, Supremacy Clause, Due Process, Takings Clause,

Excessive Fines and Equal Protection.

**Sixty-eighth Defense**

68. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

**IV.**

**PRAYER**

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiff takes nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded its costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendant in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's damages; and
6. That Defendant has such other and further relief as the Court deems appropriate.

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1 July 16, 2008

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**JURY DEMAND**

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

July 16, 2008

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